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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,372	06/08/2006	Frank Schilke	4385-053939	9406

28289 7590 03/01/2010

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
03/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,372	SCHILKE ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/24/07; 12/26/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The examiner acknowledges receipt of IDS filed 10/24/07 and 12/26/06 and preliminary amendment filed 1/12/2006. Claims 1-6 are canceled. New claims 7-16 are added. Claims 7-16 are pending.

The examiner acknowledges this application as a 371 of PCT/DE04/01571 filed 7/16/2004 and which claims priority to German application 10332680.4 filed 7/18/2003.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 7-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaffner (US 5,980,573) in view of Fox, Jr. et al. (US 5,019,096) and further in view of Neis et al. (US 5,997,544) and Kirschner et al. (US 5,942,218)

4. Shaffner describes the use of antibiotic impregnated bone cement comprised of polymethylmethacrylate (PMMA) to prevent the formation and spread of infection (see column 2, lines 4-6. 54, 55).

5. Furthermore, Fox teaches that medical devices for external or internal uses are known to introduce bacterial, viral, fungal or other undesirable infection (see column 1, lines 14-16 of Fox, Jr.) and Fox, Jr. proposes incorporating antimicrobial agents such as silver salt and chlorhexidine biguanide to produce infection resistant medical device (see column 2, lines 24-27, 35-41).

6. Bone cements containing additives such as antimicrobial agent/antibiotic agent are also known in the art (see column 6, lines 34-39 of Nies) and the antibiotic agents are sued in amounts of 5% to 20% (see Neis at column 6, line 49).

7. Also, Kirschner discloses that polyhexamethylene biguanide is used as wound antiseptic in amounts of 0.001-0.05% (see the abstract).

8. Shaffner teaches the critical element of incorporating antibiotic agent into PMMA to prevent the spread of infection so that the method of claim 7; but Shaffner does no name any specific antibiotic or antimicrobial agent for inclusion into the PMMA. But Fox teaches incorporating biguanide into medical devices so that the medical devices would resist bacterial, viral and/or fungal infection. The specific biguanide disclosed by Fox is chlorhexidine.

9. Also, Neis uses 5-20% antibiotic agent in bone cement; and Kirschner uses polyhexamethylene biguanide in amounts of 0.001-0.05. Chlorhexidine and polyhexamethylene biguanide are both biguanides as evidenced by column 6, lines 6 and 7 of Khan et al. (US 6,046,143).

10. The %amount of the biguanide in Kirschner at 0.001-0.05 is a narrower range than the amount of active in claims 10, 14 and 15 thereby meeting the limitations of these claims and for claims 7 and 11, one having ordinary skill in the art would select a specific amount of the biguanide that would provide the anticipated resistance to microbial infection. The polyhexamethylene biguanide of Kirschner meets the limitation of the biguanide of claims 7, 11 and 16. The PMMA bone cement of Shaffner meets the PMMA of claims 7 and 13-15. For claim 8, since polyhexamethylene biguanide is the recited antimicrobial agent, the limitation of claim 8 is met when polyhexamethylene biguanide is used. For claims 9 and 13, the recitation that PMMA is does not adversely affect the wound healing process is the property of the PMMA and the PMMA of Shaffner would also not adverse affect the wound healing process and in fact, Shaffner has not described the PMMA as having adverse effect on wound healing. The prosthesis implant of Shaffner meets claim 12

11. Therefore, one having ordinary skill in the art at the time the invention was made would have incorporated antimicrobial agents such as chlorhexidine and polyhexamethylene biguanide in the PMMA of Shaffner to prevent the formation and spread of infection according top the combined teachings of Shaffner, Fox, Nies and Kirschner. When using polyhexamethylene biguanide as the antimicrobial agent, one having ordinary skill in the art at the time the invention was made would have been motivated to use the biguanide in amounts of form 0.001 to 0.05 since these amounts have been shown by Kirschner to be effective as antiseptic.

12. Prior art of Interest:

13. Polymethylmethacrylate bone cement is a known product for use in orthopedic surgery or in artificial dentures (see the whole document of HAAS, with emphasis on the abstract, second full paragraph of left column of page 380).

14. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1618